

A Randomized, Controlled Study Comparing Two Standardized Closure Methods of Laparoscopic Port Sites

Kai Chen, MD, Allan S. Klapper, MD, Hayley Voige, DO, Giuseppe Del Priore, MD, MPH

ABSTRACT

Objectives: To compare octyl-cyanoacrylate tissue adhesive (OCT) with the standard suture technique for the closure of laparoscopic port sites.

Methods: This was a randomized clinical trial of 40 patients. All participants had 2 lower abdominal ports, with one port closed using OCT while the opposite port was closed with 4-0 monocryl suture. An evaluation of the wound was performed 2 weeks to 4 weeks after surgery. The Hollander Wound Evaluation Scale (HWES, including step-off of borders, contour irregularities, margin separation, edge inversion, excessive distortion, and overall appearance) was used for cosmetic evaluation. Complications, such as erythema, warmth, tenderness, drainage, and wound infection, were evaluated. Analysis of complications was performed using the chi-square test, and cosmetic evaluation including individual components of the HWES was compared with the *t* test, $P < 0.05$ considered significant.

Results: Eighty wounds were evaluated in 40 patients. The number of patients with complications including erythema (1/40 vs. 16/40), tenderness (1/40 vs. 19/40), and drainage (1/40 vs. 9/40) was lower with OCT than with sutures, respectively (all $P < 0.001$). The ports closed with OCT had higher overall HWES, ie, better cosmetic score (5.92 ± 0.05 vs 5.50 ± 0.13) and lower margin separation (1/40 vs. 10/40) but had higher contour irregularity (6/40 vs. 1/40) (all $P < 0.05$). However, skin contour irregularity was significantly better when OCT was applied using fine tissue forceps ($P = 0.002$).

Conclusion: Laparoscopic ports closed with OCT had fewer early complications, such as wound erythema, tenderness, and drainage. Ports closed with OCT had a better cosmetic appearance.

Key Words: Closure methods, Laparoscopic port, Octyl-cyanoacrylate tissue adhesive, Suture.

INTRODUCTION

The cyanoacrylate group of tissue adhesives has been studied for use in surgical procedures for over 40 years.¹ The cyanoacrylate tissue adhesives are liquid monomers that polymerize on contacting a fluid or basic medium, thereby forming a strong bond when applied to moist skin. Cyanoacrylate tissue adhesives have been available outside the United States for several decades. However, their use has been restricted to small, low-tension lacerations and incisions by the inferior mechanical properties of the butyl-cyanoacrylate, such as poor tensile strength and brittle nature. The development and introduction of the stronger and more flexible octyl-cyanoacrylate in 1998 has been a major advance in the wound closure field and has been used widely. Along with increased flexibility, it has 4 times the breaking strength of the older type cyanoacrylate. Therefore, it is indicated for use on a wider variety of wound types and ideal for study.

Diagnostic or operative laparoscopy as a minimally invasive procedure is one of the most common operations in gynecologic surgery. The benefits of minimally invasive surgery as opposed to the traditional open surgical approach are reduced pain, quicker return of oral intake, shorter hospitalization, and improved cosmetic results due to decreased scarring. There are several methods for skin closure of trocar wounds. The choice of material is often based on a surgeon's personal experience. Common procedures include closure with simple, transcutaneous, or subcuticular sutures and more recently, the tissue adhesive OCT. In addition to the above advantages of laparoscopic surgery, acceptable wound cosmetic appearance and complication are also considered important outcomes following laparoscopic surgery.

The advantages and disadvantages of these different methods have been studied to some degree.¹⁻³ Methods for closure of laparoscopic port sites vary in published series and are largely the result of surgeons' need for a rapid, economic, and reproducible technique of skin ap-

Department of Research, New York Downtown Hospital, New York, New York, USA (Dr Del Priore); Department of Obstetric and Gynecology, New York Downtown Hospital, New York, New York, USA (Drs Chen, Klapper, Voige).

Address correspondence to: Giuseppe Del Priore, MD, Division of Gynecologic Oncology, Indiana University School of Medicine, Indiana University Hospital, 550 N. University Blvd, Indianapolis IN 46202, USA. E-mail: GDelPriore@IUPUI.edu

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position. Based on previous studies,^{1,2} advantages of skin adhesives may include less time to apply and potentially good cosmetic outcomes.

The present study was designed to compare the postoperative wound characteristics of octyl-cyanoacrylate tissue adhesive (OCT) with common suture techniques for the closure of 5-mm abdominal laparoscopic port sites in the same patient.

MATERIALS AND METHODS

From March 2007 to June 2008, 40 patients who had 2 lateral lower abdominal wall 5-mm ports for elective advanced laparoscopic procedures were enrolled in this prospective, randomized controlled trial. The study was IRB approved (ClinicalTrials.gov identifier: NCT00466648). Detailed informed consent was obtained from all patients preoperatively. Patients undergoing laparoscopic surgery with at least two 5-mm ports in the lower abdomen were included in the study. Exclusion criteria included previous abdominal surgery, allergy to skin adhesives, and intraoperative enlargement of port sites.

The closure technique was randomized in each patient with one side port closed using OCT (Dermabond, Ethicon, Commerville, NJ) and the opposite port closed with single transcutaneous suture with 4–0 monofilament delayed absorbable suture. All sites were covered with a self-adhesive bandage (Bandaide, Ethicon, Commerville, NJ).

Subjects were instructed to remove the bandage after 72 hours. Postoperative wound evaluations were performed 2 weeks to 4 weeks after the procedure by the patient and a clinic physician. Signs of inflammation, such as erythema, warmth, tenderness, drainage, and wound infection, were evaluated. The Hollander Wound Evaluation Scale (HWES) was used for cosmetic evaluation. Neither the patient nor the clinic physician was informed of treatment assignment.

For statistical analysis, the chi-square test was used to compare infection, signs of inflammation, and individual components of HWES. Total HWES score was compared with the *t* test, and *P* value <0.05 was considered significant. A sample size estimate indicated that 38 subjects (76 wounds) would be needed to detect a 10% difference in the HWES score. The study was approved for 40 subjects anticipating some drop outs, but no subject was lost to follow-up.

RESULTS

All 40 eligible patients returned to the office 2 weeks to 4 weeks after the surgery for postoperation wound evaluation. Age ranged from 20 years to 68 years. Ethnicity included 40% Caucasian and 60% other minorities (Asian, Africa American, and Hispanic). BMIs ranged from 19 to 25 with an average of 22. No infection was noted after surgery in any patient.

The study shows that laparoscopic ports closed with OCT have less erythema (1/40 vs 16/40) (*P*<0.0001), tenderness (1/40 vs 19/40) (*P*<0.0001), and drainage (1/40 vs 9/40) (*P*=0.007) 2 weeks to 4 weeks after surgery compared with ports closed with suture (**Table 1**).

Approximately halfway through the study period, study personnel changed and the technique for applying OCT changed inadvertently. Early on, skin edges were loosely held together using fingertips and the OCT applied (first 12 subjects). Thereafter, fine tissue forceps were used to oppose the edges. Skin contour irregularity was significantly less in the latter half of the study (1/28 vs 5/12, *P*=0.002). A stratified analysis of the other outcome variables by study period, ie, before or after the technique change, showed no difference in other outcomes.

The individual components of HWES are given in **Table 2**. Laparoscopic ports closed with OCT had significantly less margin separation (1/40 vs 10/40) (*P*=0.004), but had more contour irregularity (6/40 vs 1/40 (*p*=0.047) compared with ports closed with suture. As detailed above in the Methods section, this difference is actually limited to the early part of the study when the OCT application technique changed. Laparoscopic port sites closed with OCT have significantly higher, ie, better, total HWES scores (*P*=0.009) compared with ports closed with suture.

Table 1.
Wound Evaluation

	Octyl-cyanoacrylate	Suture	P value
Erythema	1/40	16/40	*<0.0001
Warmth	1/40	1/40	NS
Tenderness	1/40	19/40	*<0.0001
Drainage	1/40	9/40	*0.007

^aThe number of patients with erythema (1/40 vs. 16/40, **P*<0.0001), tenderness (1/40 vs. 19/40, **P*<0.0001) and drainage (1/40 vs. 9/40, **P*=0.007) was lower with octyl-cyanoacrylate than that with sutures. The number of cases with warmth (1/40 vs 1/40) had no difference between suture and octyl-cyanoacrylate.

Table 2.
The Hollander Wound Evaluation Scale

	Octyl-cyanoacrylate	Suture	P Value
Step-off of Borders	6/40	2/40	NS
Contour Irregularities	6/40	1/40	*0.047
Margin Separation	1/40	10/40	*0.004
Edge Inversion	5/40	1/40	NS
Excessive Distortion	2/40	0/40	NS
Good Overall Appearance	40/40	39/40	NS

*The individual components of Hollander Wound Evaluation Scale. The port closed with OCT had lower margin separation (1/40 vs. 10/40, *P=0.004) but higher contour irregularity (6/40 vs. 1/40, *P=0.047). There are no differences between suture and OCT in step-off border (2/40 vs 6/40), inversion (5/40 vs 1/40), excessive distortion (0/40 vs 2/40), or overall appearance (40/40 vs 39/40).

DISCUSSION

The present study is the first prospective, randomized, controlled trial to compare transcutaneous wound closure of abdominal laparoscopic port sites in the same patient. With each of the 40 patients serving as their own control, this unique experimental design allowed us to evaluate the outcomes of laparoscopic port closure more effectively and precisely. All possible confounding variables were controlled for by this study design. This study demonstrates that laparoscopic ports closed with OCT had less erythema, tenderness, and drainage. Closures with OCT also had less margin separation and higher overall HWES scores.

Transcutaneous suture of laparoscopic port sites has been a standard procedure for wound closure for many years.³ Since absorbable sutures have been developed, subcuticular suturing of laparoscopic skin incisions has become more popular.^{4,5} Due to the additional work and expense for removal of nonabsorbable sutures, some surgeons may prefer the use of absorbable material. Other studies have found no differences with respect to wound infection, wound dehiscence, and development of hyperplastic scars or keloid between the applications of absorbable versus nonabsorbable sutures in intradermal repair.^{4,6} Another prospective randomized trial of closing laparoscopic trocar wounds⁷ indicated that transcutaneous suture had fewer postoperative complications and pain compared with subcuticular suture. Therefore, transcutaneous suture was used in closing laparoscopic trocar wounds in our study instead of subcuticular suture.

Recently, multiple studies have sometimes demonstrated that wound closure with OCT is comparable to closure with other standard wound closure devices and potentially offers additional benefits.^{1,8} Generally, OCT is indicated for any low-tension surgical incision or laceration whose edges are easily approximated with the operators' fingers or forceps, regardless of their length.¹

An earlier randomized clinical trial comparing OCT with sutures for closing 136 facial lacerations in adults was reported by Quinn et al⁹ in 1997. No differences were found between the groups in the visual analogue cosmetics scores or the percentage of wounds receiving optimal wound evaluation scores, but wound closure with the adhesive was found to be faster and less painful than suture. Dey et al¹⁰ performed a clinical trial in which 55 women undergoing gynecologic laparoscopy or laparotomy through a transverse skin incision were randomized to skin closure with either a running subcuticular stitch or OCT. Skin closure times using OCT were significantly shorter in patients undergoing either laparoscopy or laparotomy. Pain was significantly less on postoperative day 1 in the laparoscopic patients whose wounds were closed with OCT. Our study design is consistent with previous studies, demonstrating decreased pain in OCT closures.

Additional studies have also demonstrated the successful use of OCT for closure of pediatric surgical incisions^{11,12} and neurosurgical incisions of the scalp, back, and torso^{13,14} with lower rates of infection and dehiscence. Our study had similar results and showed that abdominal laparoscopic ports closed with OCT had fewer inflammatory reactions, such as erythema and drainage compared with suture.

Interestingly, a smaller study from the Greene group¹⁵ compared the surgical efficacy and wound healing characteristics of OCT with traditional suture in bilateral upper eyelid blepharoplasty, where each of 20 patients served as their own control. They found no differences in wound complications, inflammation, or final incision appearance. However blepharoplasty may not be relevant to abdominal wall surgery. Different skin tension and blood supply of the different body areas may explain differences between our results and Greene's.

Previous studies also showed that surgical incisions closed with OCT had lower dehiscence rates.¹¹⁻¹⁴ Our study showed that laparoscopic ports closed with OCT had less margin separation and better overall HWES scores. On the other hand, laparoscopic ports closed with OCT had slightly more contour irregularity compared with ports closed with suture. Most contour ir-

regularity in the OCT group was observed in the early part of our study. After the technique for applying OCT changed, only one contour irregularity was observed. Using tissue forceps with a fine tooth to approximate the wound was better than using the operator's hand and resulted in less contour irregularity. It seems that the technique for applying OCT plays an important role in contour irregularity.

CONCLUSION

Our study demonstrates that 5-mm laparoscopic port sites in the lower abdominal area closed with OCT had fewer complications and better cosmetic results in women undergoing elective gynecologic surgery. Given this and previous randomized clinical trials, our practice has changed to preferentially use OCT for 5-mm laparoscopic port-site closure.

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